

REMARKS

Claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 42-46, and 48 are presented for the Examiner's review and consideration. Claims 1, 22-25, 35, 43-45, and 48 have been amended. Claims 6, 9, 11-13, 21, 26-34, 40, 41, 47, and 49-51 are cancelled. Applicants believe the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

Election/Restrictions

Claims 6, 9, 11-13, 26-34, 47, and 49-51 were withdrawn from consideration pursuant to 37 C.F.R. §1.142(b). Applicants made a provisional election with traverse in a reply filed on May 21, 2007, but the requirement was still deemed proper. Applicants affirm the previous election without traverse and cancels claims 6, 9, 11-13, 26-34, 47, and 49-51.

Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. More specifically, the objection stated that the specification does not provide antecedent basis for the sleeve being an "insulation sleeve," nor that the sleeve is biased forward. For the reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

Referring to FIGS. 52-55 and ¶0411-¶0416 of Applicant's specification, the tubular sleeve member 1204 is discussed and shown to be slidably positionable over the force transmitting member 1172. The sleeve member includes a proximal end and a distal end, wherein the proximal end includes a channel 1206 for engaging a pin 1208 positioned on the force transmitting member. (¶0411). The channel 1206 and pin 1208 cooperate to limit the range of motion of the sleeve member 1204 over the force transmitting member 1172. (Id). In a first position, the distal end of the sleeve member 1204 is positioned to provide access to the gap between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172, for insertion and removal of the suture retainer. (Id). In a second position, the distal end of the sleeve member 1204 covers the gap

between the end surface 1194 on the energy transmission member 1170 and the flange 1192 connected with the force transmitting member 1172 for the application of ultrasonic energy. (Id.). The sleeve member 1204 acts to protect the suture and adjacent tissue from the ultrasonic energy while in the second position. (Id). Furthermore, the sleeve member 1204 could include a bias member, wherein the bias member biases the sleeve member into the first or second position. (¶0414 & ¶0415, 1st Sentences).

Accordingly, Applicant's specification discloses a tubular sleeve member that has a range of motion from a first position to a second position. In the first position, the distal end of the sleeve member provides access to the gap between the end surface of the on the energy transmission member and the flange. In a second position, the distal end of the sleeve member covers that gap. Applicant's specification also discloses that the sleeve member could include a bias member that biases the sleeve member into this first or second position. Thus, Applicant's specification provides an antecedent basis for the sleeve being capable of being biased forward. Furthermore, Applicant's specification discloses that the sleeve member acts to protect the suture and adjacent tissue from the ultrasonic energy. Thus, Applicant's specification provides an antecedent basis for the sleeve being an "insulation sleeve."

35 U.S.C. §102(b) Rejections

Claims 1, 8, 10, 14-18, and 35-37 were rejected under 35 U.S.C. §102(b) as being anticipated by Ryan (U.S. Patent 6,267,761); claims 1, 4, 5, 7, 8, 10 and 14 were rejected under 35 U.S.C. §102(b) as being anticipated by Egan (U.S. Patent 6,106,545); claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Yates (U.S. Patent 5,403,312); and claims 1, 2, 4, 5, 7, 8, 10, 14-19, 35-38, 45, and 46 were rejected under 35 U.S.C. §102(b) as being anticipated by Winston (U.S. Patent 3,513,848). For reasons set forth below, Applicants respectfully submit that these rejections should be withdrawn.

Claims 1 and 35 now recite the element of an elongated insulation sleeve slidably positionable over the second/tubular member wherein the movement of the insulation sleeve is independent of movement of the second/tubular member. Neither Ryan, Egan, nor Winston

disclose any type of insulation sleeve. Accordingly, at least this element of the claimed invention is not met by the disclosure of Ryan, Egan, or Winston.

Yates discloses an endoscopic electrocautery linear cutting and stapling instrument 10 having a body 16 coupled to a shaft 30 with a lumen extending therethrough and an end effector 50 extending from the distal end 21 of the shaft. (See FIG. 2 & Col. 5, lns. 34-41). The shaft 30 is formed of an insulative material. (Id). In FIG. 6, an enlargement of the end effector 50 of the instrument 10 is illustrated. The jaw members 32 and 34 are shown, and jaw member 32 comprises an anvil 18, a U-shaped first pole 52 extending longitudinally with respect to the jaw, and a U-shaped insulating material 55 surrounding the outside of the first pole 52. (Col. 6, lns. 1-4). As such, Yates discloses a shaft 30 that is formed of insulative material and a jaw member 32 comprising a U-shaped first pole 52 having a U-shaped insulating material 55 surrounding the first pole 52.

Thus, Yates does not show an elongated insulation sleeve slidably positionable over the second/tubular member wherein the movement of the insulation sleeve is independent of movement of the second/tubular member. The shaft 30 of Yates is formed of insulating material instead of having an insulating sleeve cover the shaft. Further, since the shaft 30 is formed of the insulating material, the insulation cannot be moved without moving the shaft 30. The U-shaped insulating material of jaw member 32 is also different than Applicant's insulation sleeve. It is U-shaped instead of being elongated. Also, it is not slidably positionable about the first pole 52, and it is not operative to move independently of the first pole 52. Accordingly, at least this element of the claimed invention is not met by the disclosure of Yates.

Accordingly, Applicants respectfully submit that independent claims 1 and 35 are patentable over Ryan, Egan, Winston, and Yates. As claims 2, 4, 5, 7, 8, 10, and 14-19 depend from claim 1, and claim 36-38, 45, and 46 depend from claim 35, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicants respectfully submit that these dependent claims are allowable over Ryan, Egan, Winston, and Yates at least for the same reasons.

35 U.S.C. §103(a) Rejection

Claims 3, 20-22, and 39-41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Winston in view of Yates, or Meade (U.S. Patent 5,478,351), or Shikhman (U.S. Patent 5,423,796); and Claims 21-23, 40-42, and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Winston in view of Shikhman. For reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

Winston in view of Yates

The rejection stated that Winston disclosed the invention as claimed with the exception of the insulating sleeve. As described above, Yates does not disclose or suggest the elements of independent claims 1 or 35. Accordingly, as claims 3, 20, and 22 depend from claim 1, and claims 39 and 41 depend from claim 35, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicants respectfully submit that these dependent claims are allowable over Winston in view of Yates.

Winston in view of Meade

Referring to FIGS. 2a-2c, Meade discloses a tool assembly 12 comprising an inner extension 20 within an outer sleeve 22 (Col. 3, lns. 62-65). The outer sleeve 22 can translate back and forth over extension 20. (Id). An insulator cover 62 covers the sleeve 22 between the distal end of rotator knob 42 and the distal end of the sleeve 22. (Col. 5, lns. 3-8). However, it is neither taught nor suggested that the insulator cover 62 is *slidably positionable* over the outer sleeve 22 or that it is capable of movement independent of the movement of the outer sleeve. In fact, in the preferred embodiment, the insulator cover 62 is attached to the sleeve 22 via a shrink fit. (Col. 5, lns. 8-9). Thus, attaching the insulator cover 62 to the sleeve 22 would make the insulator cover incapable of moving from one position to another without moving the outer sleeve.

In contrast, Claim 1, as amended, of Applicant's invention discloses an elongated insulation sleeve slidably positionable over the second member wherein the movement of the

insulation sleeve is independent of movement of the second. As such, at least this element of the claimed invention is not met by the disclosure of Meade.

Claim 35, as amended, recites the element of the insulation sleeve of Applicant's invention is slidable from a first sleeve position, covering a gapped portion of the tubular member, to a second sleeve position, uncovering the gapped portion of the tubular member. While Winston discloses a tubular member having a gapped portion, the reference does not disclose the tubular member having an insulator cover. Providing Winston with the insulator cover of Meade, however, would not provide for an insulator cover that is operative to slide from a first position, covering the gapped portion, to a second sleeve position, uncovering the gapped portion. As described above, Meade's insulator cover is not operative to move without movement of its outer sleeve because the reference neither teaches nor suggests having the insulator cover unattached to the outer sleeve. Thus, when providing Winston with the insulator cover of Meade, the insulator cover would move only when the tubular member moves. As such, the insulator cover would either have to be positioned to cover the gapped portion of the tubular member or positioned to uncover the gapped portion of the tubular member instead of being operative to cover and uncover the gapped portion by sliding the insulator cover without moving the tubular member. Therefore, this element of the claimed invention is not met by the disclosure of Meade.

Accordingly, as claims 3, 20, and 22 depend from claim 1, and claims 39 and 41 depend from claim 35, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicants respectfully submit that these dependent claims are allowable over Winston in view of Meade.

Winston in view of Shikhman

Referring to FIGS. 2 & 3, Shikhman discloses an apparatus used to penetrate body tissue having an obturator assembly 12 and a cannula assembly 14. (Col. 4, lns. 1-2). The obturator assembly 12 includes obturator housing 16 and obturator 17, which has an obturator shaft 18 and obturator tip 20. (Id). An obturator sleeve 24 is concentrically positioned about obturator shaft 18 and is *secured* to the distal end of obturator housing 16. (Id). Obturator sleeve 24 is

fabricated from an insulating material (Col. 4, lns. 17-23). The cannula assembly 14 includes cannula housing 26 and cannula sleeve 28 *secured* to the cannula housing and extending outwardly therefrom. (Id). Cannula housing 26 is configured and dimensioned to interfit with obturator housing 16 so that obturator shaft slides within cannula sleeve 28 when the two assemblies are interfitted. (Id). Cannula housing 26 also includes at least two openings, and the first opening 32 permits *rigid securement* of the proximal end of cannula sleeve 28. (Col. 4, lns. 38-42). In an alternate embodiment of the trocar assembly, obturator sleeve 24 is omitted and cannula sleeve 28 is fabricated from an insulating material. (Col. 5, lns. 6-9).

As such, Shikhman discloses an obturator sleeve 24 or cannula sleeve 28 capable of being an insulation sleeve. However, both of the sleeves are secured to their respective housings. Thus, Shikhman does not disclose an insulation sleeve that is slidably positionable over a second tubular member as discussed above. Therefore, this element of the claimed invention is not met by the disclosure of Shikhman.

Accordingly, as claims 20 and 22 depend from claim 1, and claim 42 depends from claim 35, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicants respectfully submit that these dependent claims are allowable over Winston in view of Shikhman.

Claim 48, as amended, recites the insulation sleeve element as discussed above as well as additional limitations. Accordingly, Applicants respectfully submit that claim 48 is allowable over Winston in view of Shikhman for at least the same reasons.

In light of the foregoing, Applicants request reconsideration and withdrawal of the section 103 rejections.

Allowable Subject Matter

Claims 24, 25, 43, and 44 would have been allowable if rewritten in independent form, but they were objected to as being dependent upon a rejected base claim. Applicants have rewritten the claims as required by the Examiner. Accordingly, Applicants respectfully submit that independent Claims 24, 25, 43, and 44 are allowable.

Conclusion

In light of the foregoing remarks, this application is now in condition for an examination on the merits, and early action is respectfully requested.

If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee for a one month extension of time is believed to be due for this submission and is being paid via credit card. However, please charge any required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-024).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul D. Bianco', with a large, sweeping initial 'P' and a stylized 'B' at the end.

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